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Effective Date: 06/23/99

MATERIAL SAFETY DATA SHEET

SECTION 1: CHEMICAL SUBSTANCE

PRODUCT NAME:	Anectine® Injection, USP
COMMON NAME:	succinylcholine chloride
CHEMICAL NAME:	2,2'-[(1,4-dioxo-1,4-butanediyl)bis(oxy)]bis[*N,N,N*-trimethylethanaminium] dichloride
SYNONYMS:	Anectine® Injection; Anectine Injection; Anectine® Flo-Pack®; Anectine Flo-Pack; suxamethonium chloride; suxamethonium dichloride; succinylcholine dichloride; scoline; scoline chloride; succinic acid bis (β-dimethylaminoethyl)ester
SUBSTANCE CLASS:	Neuromuscular blocking agent; depolarizing skeletal muscle relaxant

SECTION 2: HAZARDOUS INGREDIENTS

NAME	CAS/EINECS/ELINCS #	% w/v or w/w	GW LIMITS (mcg/m³)	OTHER LIMITS (mcg/m³)
Succinylcholine chloride	71-27-2		100 mcg/m³ (pure substance) 15 min STEL	Not established

SECTION 3: HAZARDS IDENTIFICATION

THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN ANECTINE® INJECTION IS HANDLED IN UNIT DOSAGE FORM.

Risk of cardiac arrest in pediatric patients following medicinal use.
Anectine® is a potent pharmaceutical agent.
Toxic if swallowed, in contact with skin, and if inhaled.
Moderately irritating to eyes and skin. May cause dermatitis.
May cause sensitization by inhalation possibly leading to asthmatic reactions.
Atmospheric concentrations in excess of the occupational exposure limit may cause muscular paralysis, irregular heartbeat, involuntary muscle twitching, respiratory failure, and death.
Contact with broken skin must be avoided. Accidental absorption into bloodstream could quickly lead to general paralysis and depressed respiratory function.
Massive overdoses could prove fatal due to respiratory failure.
Mutagenic in some test systems.

See also Section 11: "Toxicological Information".

SECTION 4: FIRST AID MEASURES

If in Eyes:	Flush immediately with large quantities of water for 15 minutes. Obtain medical attention.
If on Skin:	Flush exposed skin with water and wash thoroughly with soap and water. If irritation develops, obtain medical attention.
If Inhaled:	If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Remove person to fresh air. Obtain medical attention.
If Ingested:	If conscious, rinse mouth with water. Never give anything by mouth if unconscious. Obtain medical attention.

SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

FLASHPOINT/TEST METHOD:	Not determined.
LEL / UEL:	Not determined.
SPECIAL PROPERTIES RELATED TO FIRE HAZARD:	Emits toxic fumes under fire conditions.
STORAGE OR HANDLING CONDITIONS TO BE AVOIDED:	Not determined.
EXTINGUISHING MEDIA:	Water Spray, Multipurpose Dry Chemical.
FIRE-FIGHTING PROCEDURES:	Wear full protective clothing and use self-contained breathing apparatus (SCBA).

SECTION 6: SPILL AND LEAK PROCEDURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills. (See Section 8, "Exposure Controls / Personal Protection" for guidance).

For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by carefully wiping or by using a suitable absorbent and place in a labeled, sealed container for disposal. Wash spill area (floor or other contact surfaces) thoroughly with soap and water.

SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid contact with eyes, skin, and clothing. Minimize generation and accumulation of aerosols containing this substance. Use only in a well-ventilated area; aerosol-generating procedures should be conducted in a laboratory fume hood or with other suitable local exhaust ventilation. Clean surfaces that may be contaminated with the substance, such as hands, skin, and equipment surfaces, before leaving the work area. Properly identify (signage and labeling) potential hazards in designated areas.

Aseptic techniques should be used to prepare the diluted product.. Succinylcholine is acidic (pH 3.5) and should not be mixed with alkaline solutions having a pH greater than 8.5.

SECTION 7: HANDLING AND STORAGE (cont'd)

HANDLING: Anectine® Injection is an acidic solution (pH= 3.5) and appropriate personal protective measures should be used when handling or administering the product (See Section 8, "Exposure Controls/Personal Protection" for guidance). Admixtures of Anectine® Injection should be prepared for single patient use only. The unused portion should be discarded.

STORAGE: Anectine® Injection should be stored in a refrigerator at 2° to 8°C (36° to 46°F) to preserve potency and must be used within 24 hours after preparation. The multi-dose vials are stable for up to 14 days at room temperature without significant loss of potency.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: No special ventilation requirements for therapeutic dosage and administration. In areas of high aerosol concentration, use process containment, local exhaust ventilation, or other engineering control devices to control airborne levels to below occupational exposure limits (OEL).

PERSONAL PROTECTION:

Respiratory: Not required under normal conditions of therapeutic use and storage. For aerosol-generating procedures and in the absence of sufficient engineering controls, use NIOSH-approved respiratory protection. See Section 5 – "Fire / Explosion Hazards & Fire-Fighting Measures" for respiratory protection in the event of a fire.

Eye: Workers should wear adequate eye protection to prevent eye contact. Workers should wear goggles if splash hazard exists.

Clothing: Adequate protective clothing should be worn to prevent occupational skin contact.

Gloves: Impermeable gloves should be worn when routine handling or spill cleanup may result in skin contact. Dispose of gloves according to federal, state, and local regulations.

WORK PRACTICES: Special care should be taken to ensure that contaminated clothing, equipment, and surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly after handling this material. Contaminated clothing should be disposed of or cleaned. Potentially contaminated clothing should be packaged for laundering to prevent exposure of laundry personnel. Extra precautions are necessary for workers with non-intact or broken skin.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

APPEARANCE AND ODOR: Anectine® Injection is a sterile, non-pyrogenic solution for injection supplied in single-dose vials (20 mg/mL) or multi-dose vials (10 mL), box of 12 vials.

PHYSICAL STATE (liquid/solid/gas): Liquid.

MELTING POINT (deg. C): The melting point for succinylcholine chloride, the active ingredient in Anectine® Injection, is 156° to 163°C (312° to 325° F).

BOILING POINT (deg. C): Not determined.

SOLUBILITY/MISCIBILITY (% w/v): Not determined for Anectine® Injection. The solubility of succinylcholine chloride, the active ingredient in Anectine®, is about 1 g/mL at 25°C in water.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES (cont'd)

SOLUBILITY/MISCIBILITY (% w/v): Succinylcholine chloride is unstable in alkaline solutions but relatively stable in acid solutions, depending upon the concentration of the solution and the storage temperature. The pH of a succinylcholine chloride solution is 3.5.

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: Single-dose vials of Anectine® Injection are stable when refrigerated. Anectine® Injection multi-dose vials are stable for up to fourteen days when stored at room temperature

CONDITIONS TO AVOID: Anectine® Injection is an acidic solution (pH= 3.5) and should not be mixed with alkaline solutions with pH>8.5.

INCOMPATIBILITY WITH OTHER MATERIALS: Not determined for Anectine®. No known incompatibilities have been identified for succinylcholine chloride, the active ingredient in Anectine®.

HAZARDOUS DECOMPOSITION PRODUCTS: Hazardous decomposition products of Anectine® Injection have not been determined. Thermal decomposition products of succinylcholine, the active ingredient in Anectine®, include toxic and/or corrosive oxides of nitrogen and carbon, and hydrogen chloride.

HAZARDOUS POLYMERIZATION: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN ANECTINE® INJECTION IS HANDLED IN UNIT DOSAGE FORM.

PHARMACOLOGICAL ACTIVITY: Succinylcholine chloride is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

OCCUPATIONAL EXPOSURE LIMITS: For succinylcholine chloride, the active ingredient in Anectine®, the Glaxo Wellcome estimated safe working level is a short term exposure level (STEL,15 minute time-weighted average) of 100 mcg/m^3.

ACUTE TOXICITY: Acute expose to Anectine® may produce symptoms associated with its pharmacological properties, including deficits in coordinated muscular activity up to and including body-wide muscular paralysis, the loss of control of the muscles involved in breathing, and cardiac irregularities.

Occupational exposure to Anectine® may produce adverse effects similar to those observed during its therapeutic use (see "Clinical Safety", below). Succinylcholine administration has been associated with the acute onset of malignant hyperthermia, manifested by spasm of the jaw muscles, generalized rigidity, extremely high body temperature, rapid breathing, rapid heartbeat and/or blotchy blue discoloring of the skin. Overdoses of Anectine® may produce extended periods of neuromuscular block. This may be manifested by skeletal muscle weakness or involuntary muscle twitching, decreased respiratory function, cardiac irregularities, or respiratory failure.

SECTION 11: TOXICOLOGICAL INFORMATION (cont'd)

ACUTE TOXICITY (cont'd): Approximate lethal doses of succinylcholine chloride following single administration were:

Mouse 430 mcg/kg (iv)
Rabbit 240 mcg/kg (iv)

REPEAT DOSE TOXICITY: Succinylcholine chloride produced no chronic toxic effects in rats when administered intraperitoneally for two weeks. However, repeated occupational exposure to succinylcholine chloride may produce effects similar to those observed in its therapeutic use (see "Clinical Safety", below).

IRRITATION: Succinylcholine chloride, the active ingredient in Anectine®, is moderately irritating to the eyes and skin and has been reported to cause contact dermatitis.

SENSITIZATION: Animal and human clinical data indicates that succinylcholine chloride, the active ingredient in Anectine®, may be allergenic and may cause respiratory sensitization.

REPRODUCTIVE EFFECTS : Animal reproduction studies have not been conducted with succinylcholine chloride, the active ingredient in Anectine®.

For recommended dosage and administration, Anectine® is classified as "Pregnancy Category C". Small amounts of Anectine® are known to cross the placental barrier. It is not known whether Anectine® can cause fetal harm when administered repeatedly to a pregnant woman. Under normal circumstances (single maternal dose at delivery of 1mg/kg), Anectine® should not endanger the fetus. A higher proportion of patients may be expected to show increased sensitivity (prolonged apnea) to succinylcholine when pregnant than when not pregnant. Therefore, Anectine® should be given to a pregnant woman only if clearly needed.

It is not known whether Anectine® is excreted in breast milk. Because many drugs are excreted in human milk, precautions should be taken to limit exposure to this substance while pregnant or nursing. Medical evaluation of exposure and attention to compliance with standard operating procedures and/or other workplace health and safety directives is advised.

GENOTOXICITY: Scientific literature references indicate that succinylcholine chloride, the active ingredient in Anectine®, was genotoxic in the following in vitro systems: mammalian cell culture and mouse micronucleus test. However, no chromosomal damage has been observed in humans receiving clinical doses of Anectine®.

CARCINOGENICITY: Carcinogenesis studies have not been performed for succinylcholine chloride.

CLINICAL SAFETY: Adverse reactions to Anectine® consist primarily of prolongation of its pharmacological actions. Anectine® causes profound muscle relaxation resulting in respiratory depression to the point of apnea. Hypersensitivity reactions, including anaphylaxis, may occur in rare instances. The following additional adverse reactions have been reported: cardiac arrest, malignant hyperthermia, arrhythmias, bradycardia (slow heartbeat), tachycardia (rapid heartbeat), hypertension (increased blood pressure), hypotension (decreased

SECTION 11: TOXICOLOGICAL INFORMATION (cont'd)

CLINICAL SAFETY (cont'd): blood pressure), hyperkalemia (elevated blood potassium), prolonged respiratory depression or apnea, increased intraocular pressure, muscle fasciculation, jaw rigidity, increased intercranial pressure, increased intragastric pressure, postoperative muscle pain, rhabdomyolysis with possible myoglobinuric acute renal failure, excessive salivation, and rash.

Although uncommon in clinical use, the potential for histamine release exists following exposure to Anectine®. Characteristic symptoms of histamine release may include: flushing, hypotension (low blood pressure), and bronchoconstriction.

SECTION 12: ECOLOGICAL INFORMATION

ENVIRONMENTAL EFFECTS: Environmental effects testing is currently underway. Until environmental effects have been determined, dispose of unused compound or process wastes by incineration.

ENVIRONMENTAL TEST RESULTS:

STUDY NAME	RESULTS	COMMENTS
Water Solubility:	Not available	
Hydrolysis Rate:	Not available	
Vapor Pressure:	Not available	
Dissociation Constant:	Not available	
n-Octanol/Water Partition Coefficient:	Not available	
UV/Visible Spectrum:	Not available	
Aerobic Biodegradation (water)	Not available	
Aerobic Biodegradation (soil)	Not available	
Soil Absorption/Desorption:	Not available	
Activated sludge respiration inhibition test	Not available	
Five day bacterial inhibition	Not available	
Acute toxicity to Daphnia	Not available	

SECTION 13: WASTE DISPOSAL

ROUTINE: Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.

ACCIDENTAL RELEASE: Clean up spills immediately, observing precautions in Section 8 - "Personal Protection". Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 14: TRANSPORTATION INFORMATION

Component 1 or Formulation 1: Anectine® Injection

US Department of Transportation
Proper Shipping Name: Not regulated in transportation

IATA/ICAO
Proper Shipping Name: Not regulated in transportation

SECTION 14: TRANSPORTATION INFORMATION (cont'd)

IMDG
Proper Shipping Name: Not regulated in transportation

RQ: None Marine Pollutant: No

SECTION 15: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Succinylcholine chloride is not listed under the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations, 1997. However, suitable labeling would be:

Indication of Danger (Hazard Symbol): Toxic

Risk Phrases: R23/ 24/ 25: Toxic by inhalation, in contact with skin and if swallowed.
R42: May cause sensitization by inhalation.

Safety Phrases: S22: Do not breathe dust.
S24/ 25: Avoid contact with skin and eyes.
S36/ 37/ 39: Wear suitable protective clothing, gloves and eye/ face protection.
S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

OTHER LEGISLATION: Not determined.

SECTION 16: OTHER INFORMATION

REVISION DATE: 06/23/99 SUPERSEDES: 10/31/94